

REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

Claims 24 has been amended to recite:

A method for the detection of an invasive fungal infection ~~diagnosis of a fungal infection~~ in a human patient comprising:

(a) assaying mucosal secretions or urine of the patient with suspected invasive infection with at least one antibody reactive with a fungal ~~Candida~~ $\beta(1-3)$ glucan – epitope and/or a fungal $\beta(1-3)(1-6)$ – glucan epitope in free form or available in cell wall fragments of fungi ~~*C. albicans* or *C. neoformans*~~, or on the cell surface of fungi ~~*C. albicans*, *C. parapsilosis*, *C. krusei*, *C. glabrata* and/or *C. neoformans*~~, wherein the fungal infection is Candida vaginitis or mucocutaneous candidiasis and

(b) evaluating the levels of $\beta(1-3)$ glucans and/or $\beta(1-3)(1-6)$ glucans in the secretions or urine. Support for this terminology is found at page 1, lines 7-13; page 2, lines 25-37; page 3, lines 1-11 and lines 23-37.

Claim 28 has been similarly amended.

In the Office Action of March 12, 2008, the Examiner took the following actions to which Applicant herein makes response: (1) noted that applicant had listed incorrect status identifiers for the claims; (2) withdrew the objection to the trademark usage; (3) objected to the disclosure because of usage of incomplete references to genera of organisms in the specification; (4) objected to the pending claims and stated that the organism names should be italicized; (5) withdrew certain section 112 and 102(b) rejections but maintained the rejection of claims 24 and 28 under 35 USC 112, first paragraph with respect to the written description requirement stating that the claims use antibodies that bind to multiple organisms to differentiate between the organisms, and there is not sufficient information in the specification to describe the antibodies or antigens; (6) maintained the rejection of claims 24 and 28 under 35 USC 112, first paragraph with respect to the enablement requirement; and (7) newly rejected claims 24 and 28 under 35 USC 112, second paragraph with respect to the phrase “wherein the

fungal infection is *Candida vaginitis* or mucocutane candidiasis” and suggested language that would overcome this rejection only, as well as to various other terminology. These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 24-25 and 28 now pending in the application.

(1) Incorrect status identifiers for the claims

Applicant has corrected the incorrect items pointed out by the Examiner.

(2) Objection to the trademark usage

This objection has been withdrawn.

(3) Objection to the disclosure because of usage of incomplete references to genera of organisms in the specification

Applicant has reviewed the specification and has corrected all incomplete references found in this search. Should any incomplete references have been missed in this review, Applicant respectfully requests an Examiner’s amendment for such correction.

(4) Objection to the pending claims regarding italicizing of organism names

Applicant has corrected the italicizing of organism names in the application wherever this was found to be incorrect.

(5) Rejection of claims 24 and 28 under 35 USC 112, first paragraph with respect to the written description requirement stating that the claims use antibodies that bind to multiple organisms to differentiate between the organisms, and there is not sufficient information in the specification to describe the antibodies or antigens

Applicant respectfully reiterates that it is not the specific identify of the antibodies prepared by Applicant that is the subject of the claims herein, but rather the claims as amended herein may be accomplished by one of ordinary skill in the art using standard antibody creation and selection technology. This is clear from Applicant’s description of the known related methods and results found in the literature, e.g., at page 15 of the

specification. It is the particular method of use of antibodies obtainable by standard techniques as a diagnostic technique not previously used for diagnosis of fungal infections that is being sought to be patented. It is not the specific nature of the antibodies, but rather the fact that antibodies that react to a generally common structure found in fungi are being used to analyze mucosal secretions or urine of the patient with suspected invasive infection. It is clear that if someone using the method of the invention found an unusually high level of reactivity with antibodies prepared as in the specification herein, such reactivity would be closely correlated with a large number of fungi in the substance being analyzed. In a human being, it would likely that an unusually high number of fungi would be a useful preliminary diagnostic tool to let the medical practitioner be aware that there might be a medical problem, particularly if the antibody was against a common fungal component as in the invention herein. False positives would be unlikely, as one would be unlikely to have high concentrations of *non*-pathogenic fungi or related organisms in their bodily liquids. The increased growth of pathogens in human fluids, and the resulting symptoms, are almost by definition the reasons that certain microorganisms are classified as pathogens. As described in the specification, the novelty of the invention lies in the recognition of surface-localized betaglucan in yeast cells and the use of antibodies thereto as a method of determining levels of yeast (fungal) cells.

Further Applicant also points out that the claims as amended herein do relate to methods of detection of fungal infections. It is clear from the specification herein that antibodies to the glucans as claimed are useful in detecting the presence of fungi in liquids, and therefore, there is sufficient information in the specification to describe the antigens and antibodies that *will work in the claimed invention herein*.

Applicant therefore respectfully submits that claims 24 and 28 are patentable under 35 USC 112, first paragraph.

(6) Rejection of claims 24 and 28 under 35 USC 112, first paragraph with respect to the enablement requirement

Applicant respectfully incorporates herein the above remarks, and submits for the reasons given above, that claims 24 and 28 are also enabled by the specification herein.

Thus, one of ordinary skill in the art would well know, from the literature cited in the application and from the examples provided in the application by Applicant, how to obtain antibodies with the requisite reactivity, i.e., “reactive with a fungal $\beta(1-3)$ glucan – epitope *and/or* a fungal $\beta(1-3)(1-6)$ – glucan epitope in free form *or* available in cell wall fragments of fungi” (claim 24 as amended, emphasis added), and would know how to test human urine or mucosal secretions with the antibody.

Applicant therefore respectfully submits that claims 24 and 28 are patentable under 35 USC 112, first paragraph.

(7) Rejected claims 24 and 28 under 35 USC 112, second paragraph

The Examiner stated that the term “wherein the fungal infection is *Candida* vaginitis or mucocutane candidiasis”. This terminology has been removed from claims 24 and 28.

The Examiner also stated that it was not clear whether the modifier “*Candida*” was meant to apply to both glucans. The pending claims now state that each epitope is a fungal epitope.

The organism “*C. neoformans*” no longer appears in the claims, and its use elsewhere in the application has been made clearer by replacing with “*Cryptococcus neoformans*”.

Applicant therefore submits that claims 24 and 28 are patentable under 35 USC second paragraph.

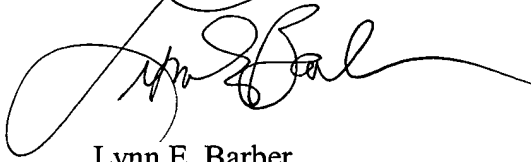
Conclusion

For all the foregoing reasons, claims 24 and 28 are submitted to be fully patentably distinguished over the cited reference and in allowable condition. Favorable consideration is therefore requested.

No new claims have been added to the previously pending claims. It is therefore believed that no fee is required for the presentation of this amendment except for the separately submitted Petition for Extension of Time. Any additional amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant’s attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lynn E. Barber", with a long, sweeping horizontal line extending to the right.

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Enclosures:

Petition for Extension of Time and fee